



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,647	03/07/2001	Dieter Hochrainer	I/1060-1-C1	7374

23703 7590 07/29/2003

BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD, CT 06877

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 07/29/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/800,647

Applicant(s)

HOCHRAINER ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Priority Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on May 12, 2003 has been entered. Claims 31-40 are now pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the claim amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim 31 uses the closed transitional phrase "consisting of," therefore, no additional elements may be added to the scope of claim 31. However, claims 38-39 further limit the scope of claim 31 to contain a pharmaceutically acceptable filler. Accordingly, the scopes of claims 38-39 are broader than their respective base claim.

Claim Rejections - 35 USC § 103

Claims 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Etani US Patent 4,880,547.

Etani discloses polymeric capsules having two hemispheres as depicted in figure 2 or other spherical shapes such as eggshaped capsules. Thus, the capsules of meet the physical characteristics of the instant capsules. The capsules of Etani consist of high density polyethylene, thus, inherently meets the density, steam permeability and compressability requirements of the instant claims, because it is made of the same type polymers as instantly claimed and taught. The capsule of Etani can further contain

Art Unit: 1617

various types of chemical including herbicides, insecticides, micronutrients etc... which are considered to be pharmaceutically acceptable fillers (see col 9-12). Ethani explicitly indicates that dry powders may be incorporated into the shells for suitable utility (see col 5, lines 43-64). As recognized by the Applicants Etani fails to teach the instant elongation limitations.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell, 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Accordingly, absence the showing of criticality, it would have been *prima facie* obvious to optimize the elongation value of Etani's capsules by routine experimentation, because the ordinary artisan would have had a reasonable expectation of success in achieving the desirable delivery of agent of choice by modifying the elongation size of Etani's capsules.

Claims 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Etani US Patent 4,880,547 and EP 0143,524 (EP '524) in view of Jones US Patent 4,892,766, ('547) and Lee et al US Patent 5,795,591.

The teachings of Etani are described above. Etani renders obvious the limitations of claims 31-39 for the reasons set forth above. Etani doesn't use the his compositions to carry the instantly claimed pharmaceutical agents of claim 40.

EP '524 dicloses two-part capsules having suitable diameters of 2.5-3.5 to 1 mm for medicinal use. The capsule of EP '524 is not made of high-density polyethylene polymers.

Jones discloses hard gelatin capsules shells comprising fibrous material, which do not split after storage when filled with deliquescent materials (see abstract, claims 1-10). Although, Jones invention is directed to hydrophilic shells but he teach that the water permeability of said shells may be modified when high-density polyethylene polymers are incorporated into the fibrous material (see col 2, lines 32-37).

Finally, Lee is solely relied upon to show that non biodegradable polyethylenic polymers are readily used for in vivo administration of various drugs such as atropine sulfate, dexamethasone etc.. (see col 4, lines 49-50; col 8, line 61-col 9, line 30).

Accordingly, even though Etani does not use its capsules for medicinal use, it would have been obvious to one of ordinary skill in the art at the time of invention the to optimize the size of high density polyethylene capsules of Etani for in vivo use, as suggested by EP '524 and further use them as carriers of pharmaceutical powders, because carrying powdered drugs in capsule delivery systems are conventional, and as shown by Etani and Lee, high density polyethylene polymers are suitable for therapeutic utility and can be conventionally manipulated into a suitable capsular shape.

Response to Arguments

Applicant's arguments with respect to Etani have been fully considered but are not found persuasive. Applicant argues that unlike instant capsules, Etani's capsules contain holes. This argument is not persuasive because the scope of the claims do not exclude such capsules that have holes.

With respect to the obviousness rejection, Applicant argues that none of the cited references teach capsules for inhalation use. In reply Examiner states that the intended use does not impart patentability.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The

Art Unit: 1617

fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
July 27, 2003



RUSSELL TRAVERS
PRIMARY EXAMINER